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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/828,700 | 04/21/2004 | Chih-Chiang Yang | P464.312-0001 | 5387 |
| 164 7590 04/04/2007 KINNEY & LANGE, P.A. THE KINNEY & LANGE BUILDING 312 SOUTH THIRD STREET MINNEAPOLIS, MN 55415-1002 | | | EXAMINER KRISHNAN, GANAPATHY | |
| | | | ART UNIT 1623 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 04/04/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/828,700

Applicant(s)

YANG ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/13/2006
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6-7, 11 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 3 and 11 it is not clear what applicants intend by the recitation, "hydroxy-cyclodextrin", since cyclodextrins have hydroxyl groups. Do applicants intend any other specific hydroxyalkyl cyclodextrin?

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitations

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alkyl polyglycosides and N-alkyl glucamines, and the claim also recites (C₂-C₆)alkyl polyglycosides and N-(C₆-C₂₄)alkyl glucamines, which is the narrower statement of the range/limitation. The same recitation is also seen in claim 14.

In claims 6-7 and 14-15 it is not clear what applicants intend by the terms monostearate type surfactants. The metes and bounds of the claims cannot be determined.

Claims 6 and 14 recite the term derivatives. In the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of derivatives of this invention, the identity of the said derivatives would be difficult to describe and the metes and bounds of said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193).

Bodor teaches a composition comprising a cyclodextrin inclusion complex of 17-beta-Estradiol (steroidal active agent, estrogen) with 2-hydroxypropyl-beta-cyclodextrin and aqueous methanol (alcohol, limitation of claim 6) as the nonionic surfactant (noisome; page 186, first and

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second paragraphs; limitations of claims 1-3). The composition is prepared in a manner similar to the method as described in example 5 at page 13 of the instant specification and should produce a composition comprising a noisome as instantly claimed.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193).

Bodor teaches a composition comprising a noisome as explained above. Bodor also teaches the effect of the cyclodextrin on the permeability of 17-beta-Estradiol through mouse skin (page 193, Table 4). It can be seen from Table 4 that permeation of 17-beta-Estradiol is enhanced (or facilitated) by using it in combination with 2-hydroxypropyl-beta-cyclodextrin and glycerol, another alcohol (non-ionic surfactant). This teaching is seen to meet the limitations of instant claim 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193) in view of Siguroardottir et al (Drug Development And Industrial Pharmacy, 1994, 20(9), 1699-1078).

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Bodor teaches a composition comprising a cyclodextrin inclusion complex of 17-beta-Estradiol (steroidal active agent, estrogen) with 2-hydroxypropyl-beta-cyclodextrin and aqueous methanol (alcohol) as the nonionic surfactant (noisome; page 186, first and second paragraphs). The composition is prepared in a manner similar to the method as described in example 5 at page 13 of the instant specification and should produce a composition comprising a noisome as instantly claimed. Bodor, teaches the preparation of similar compositions using other steroidal active agents too (see page 186 under materials). However, Bodor does not teach compositions comprising the other cyclodextrins

Siguroardottir et al, drawn to similar compositions as Bodor, teach compositions comprising other nonionic surfactants like glyceryl monostearate, etc. (page 1701, last paragraph through page 1702, first paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising a noisome comprising the cyclodextrin derivatives and the surfactants as instantly claimed since the compositions comprising analogous active agents are seen to be taught in the prior art.

One of skill in the art would be motivated to make the compositions comprising the various active agents as instantly claimed since considerable amounts of hydroxypropyl beta cyclodextrin has been found to penetrate the skin barrier due to the action of surfactants and would look for other cyclodextrins and surfactant combinations that penetrate the skin barrier and hence help transport the steroidal active agent through the skin (Siguroardottir, page 1700, last paragraph).

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It is well within the purview of one of ordinary skill in the art to adjust ratios of the active agents in order to optimize the composition and extend the scope.

Claims 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193) in view of Loftsson (US 5,472,954).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The instant claims are drawn to a method producing a composition if instant claim 1.

Bodor teaches a composition comprising a cyclodextrin inclusion complex of 17-beta-Estradiol (steroidal active agent, estrogen) with 2-hydroxypropyl-beta-cyclodextrin and aqueous methanol (alcohol) as the nonionic surfactant (as recited in instant claim 6; noisome; page 186,

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first and second paragraphs). The composition of Bodor is prepared by forming an inclusion complex of 17-beta-Estradiol (steroidal active agent, estrogen) with 2-hydroxypropyl-beta-cyclodextrin and then mixing the complex with a vesicle solution of the alcohol (non-ionic surfactant). However, Bodor does not teach the mixing of the two solutions in a ratio of 1.0 to 25.0, drying of the resulting mixture, grinding of the cyclodextrin and the steroid or freeze-drying as instantly claimed. The composition is prepared in a manner similar to the method as described in example 5 at page 13 of the instant specification and should produce a composition comprising a noisome as instantly claimed.

Loftsson, drawn to cyclodextrin complexation, teaches lyophilization (freeze drying) and grinding of an analogous complex of cyclodextrin and cellulose derivative (col. 28, lines 45-54). One of ordinary skill in the art will recognize that the same process step can be used for the process as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising a noisome via the steps as instantly claimed since the same process steps are taught in the prior art using similar active agents.

One of skill in the art would be motivated to use the process as instantly claimed since the process steps of the prior art involve simple steps involving mixing the active agents and are easy to carry out/manipulate.

It is well within the purview of one of ordinary skill in the art to adjust process parameters, ratios of the active agents and also substitute other cyclodextrins, surfactants in the process in order to optimize the process and extend the scope.

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Conclusion

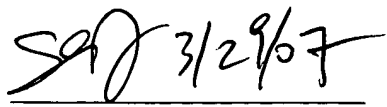
Claims 1-19 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Shaojia Jiang
Supervisory Patent Examiner
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